

1K970116

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MYO-TRONICS, INC.



**510(k) SUMMARY**

**1. Submitter's Information**

Date of Submission: January 10, 1997  
Submitter's name and address:

Myo-tronics, Inc., 15425 - 53 Ave. So., Tukwila, WA 98188  
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Contact Name: Mr. Fray Adib

**2. Device Trade Name:** ESG-1 Electrosonogram or Sonograph  
**Common name:** Temporomandibular Joint Sound Recorder  
**Classification name:** Unclassified

**3. Myo-tronics' ESG-1 Electrosonogram is substantially equivalent to: SONOPAK/QS manufactured by BioResearch of Milwaukee, Wisconsin.**

**4. Description of the device:**

ESG-1 Electrosonogram is a non-invasive device that measures and records sounds emitted from the temporomandibular joint along with the relative position of the jaw as a means of assessing the status of the temporomandibular joint.

**5. The ESG-1 Electrosonogram has the same technological characteristics as the above mentioned predicate device.**

WORLD LEADERSHIP FOR OVER 25 YEARS

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